K090931

510(k) SUMMARY

DEC 15 2009

Applicant and Owner	W&H Dentalwerk Buermoos GmbH Ignaz-Glaser-Strasse 53 A - 5111 Buermoos Austria Tel.: 0043 -6274 / 6236 -297 Fax: 0043 -6274 / 6236 -234
Contact Person	Johann Georg SCHARL
Date of Preparation	March 20th, 2009
Device Name	Cordless ENDO-Handpiece "ENTRAN" (W&H) Cordless ENDO-Handpiece "S5 ENDO Motor" (Sendoline)
Classification Name	Handpiece, Direct Drive, Ac-Powered
Regulation Number	21 CFR872.4200
Product Code	EKX
Predicate Devices	"Tri Auto ZX", J. Morita USA Inc., K970339
Device Description	The cordless ENDO-handpiece EB-300 (EB-300 S) consists of the cordless drive EB-3 H (EB-3 SH) and the special contra-angle attachment EB-16 (EB-16 S), intended for mechanical rotating root canal preparation. The drive is fitted out with a 3.7 V Li-Ion battery, which can be re-charged using the provided charging station. By means of the different buttons on this drive, the user controls the various functions, such as on / off, speed, torque and auto-reverse / auto-forward mode. The drive and the contra-angle attachment are connected via a special coupling, based on ISO 3964. The handpiece´s application is intended in dentistry.
Intended Use:	Modular electrical system for mechanical preparation of the root canal, using a special root canal instrument (>>ENDO file<<), which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.
Technological Characteristics	W&H´s Handpieces represent a revised and improved version of the predicate device. The main technical characteristics have been retained unchanged. The new products´ advantages can be found above all in its usability: less weight and smaller size, better balanced, ergonomically designed.
Comparison of the device to the predicate device	The intended use, technological characteristics, performance parameter and material are very similar to the predicate device. The new devices are substantially equivalent to the predicate devices.
Performance Testing	Bench testing results demonstrate substantially equivalence
Clinical Testing	Clinical data were not needed for these new products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Johann Georg Scharl
Regulatory Affairs Manager
W & H Dentalwerk Buermoos GmbH
Ignaz-Glaser-Strasse 53
A – 5111 Buermoos
AUSTRIA

DEC 15 2009

Re: K090931
Trade/Device Name: Cordless ENDO Handpiece "ENTRAN" (W&H)
Cordless ENDO Handpiece "S5 Endo Motor" (Sendoline)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: November 25, 2009
Received: November 30, 2009

Dear Mr. Scharl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name:

Cordless ENDO handpiece "ENTRAN" (W&H)
Cordless ENDO handpiece "S5 Endo Motor" (Sendoline)

Indication for Use:

Modular electrical system for mechanical preparation of the root canal, using a special root canal instrument (>>ENDO file<<), which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Betz DDS for Dr. K.P. Mulloy (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090931